UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen - ASD-ADHD Products Liability Litigation	22MD3043 (DLC) 22MC3043 (DLC)
This Document Relates To: All Pending Cases	OPINION AND ORDER

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DENISE COTE, District Judge:

This Opinion grants summary judgment to the defendants in pending cases in this products liability MDL. Prior Opinions have excluded testimony from the plaintiffs' experts on the issue of general causation. The plaintiffs have resisted summary judgment by arguing that they can meet their burden of establishing general causation by using certain statements made by one of the defendants' experts. For the following reasons, that effort fails and the defendants are entitled to summary judgment.

Background

Familiarity with prior Opinions in this MDL is assumed. This Opinion summarizes only those facts relevant to this motion.

This litigation began in 2022, when plaintiffs -- children, parents, and guardians who alleged injuries from the development in children of autism spectrum disorder ("ASD") and attention deficit hyperactivity disorder ("ADHD") due to a mother's prenatal use of acetaminophen -- began to file products liability lawsuits in federal courts. Plaintiffs sued the manufacturer of Tylenol (Johnson & Johnson Consumer Inc.) and retailers of store-branded acetaminophen products, alleging that

the defendants' labeling practices for acetaminophen were deficient under various state laws.

In October of 2022, the Judicial Panel on Multidistrict Litigation consolidated plaintiffs' cases and transferred the cases to this Court under 28 U.S.C. § 1407. This MDL has included hundreds of cases. Motions to dismiss individual actions on the ground of preemption were denied in November 2022 and April 2023.[1] Additional motions to dismiss were addressed in April and May of 2023.[2]

All fifty states require some evidence of general causation in products liability cases involving medical issues. See In re Mirena IUS Levonorgestrel-Related Products Liability Litigation, 982 F.3d 113, 124 (2d. Cir. 2020) ("Mirena II"). At a pretrial conference on December 2, 2022, the Court proposed, and the parties agreed, to conduct discovery related to general causation first; if the plaintiffs' experts on the issue of general causation survived Rule 702 motions, the remainder of

[1] In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022); 2023 WL 3026412 (S.D.N.Y. Apr. 20, 2023).

[2] In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3045802 (S.D.N.Y. Apr. 21, 2023); 2023 WL 3126589 (S.D.N.Y. Apr. 27, 2023); 2023 WL 3126636 (S.D.N.Y. Apr. 27, 2023); 2023 WL 3162623 (S.D.N.Y. Apr. 28, 2023); and 2023 WL 3467057 (S.D.N.Y. May 15, 2023).

discovery would proceed. The initial Rule 702 motions were fully submitted on October 20, 2023. The plaintiffs had identified five experts to the defendants and the defendants had moved to strike pursuant to Rule 702 the opinions of each of those experts. Oral argument on the defendants' motions to strike the plaintiffs' expert reports was held on December 7, 2023.

On December 18, 2023, the First Daubert Opinion was issued.[3] The 148-page Opinion excluded the proposed testimony of the five experts for the plaintiffs: Drs. Andrea Baccarelli, Robert Cabrera, Eric Hollander, Brandon Pearson, and Stan Louie, each of whom was tendered in support of a transdiagnostic opinion that prenatal exposure to acetaminophen causes both ASD and ADHD.[4] The plaintiffs' Rule 702 motions to exclude defendants' experts were denied as moot. Pursuant to an Order to Show Cause process, final judgment was entered in approximately 550 cases

[3] In re Acetaminophen - ASD-ADHD Prods. Liabl. Litig., --- F.Supp.3d ---, No. 22md3043 (DLC), 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023).

[4] Dr. Hollander defined a transdiagnostic process as a "mechanism that underlies and connects a group of disorders that transcends traditional diagnostic boundaries" and opined that "it is appropriate to review the body of evidence that measures symptoms of neurodevelopmental disorders and to not limit the analysis to studies that focus on ASD and ADHD as specified outcomes when evaluating the potential causal association between prenatal [acetaminophen] exposure and ASD and ADHD in offspring."

in the MDL, specifically those cases in which a Short Form Complaint was served on or before January 11, 2024. Those plaintiffs have appealed.

On February 1, the plaintiffs in several newly-filed actions advised the Court that they had retained their own expert, Dr. Roberta Ness, who offered opinion testimony on general causation as to ADHD only. Over the objection of the defendants, the Court permitted these plaintiffs to substitute Dr. Ness as their general causation expert and set a schedule for further Rule 702 briefing. Defendants' Rule 702 motion to exclude opinions offered by Dr. Ness was fully submitted on June 11, 2024. An 84-page Opinion and Order of July 10 granted defendants' motion. In re Acetaminophen - ASD-ADHD Prods. Liabl. Litig., No. 22md3043 (DLC), 2024 WL 3357608 (S.D.N.Y. Jul. 10, 2024) ("Second Daubert Opinion").

An Order of July 11 required plaintiffs to show cause by July 25 why final judgment under Rule 56 should not be entered in each pending member case of this MDL on the ground that the plaintiffs in these member cases have failed to offer admissible evidence that prenatal exposure to acetaminophen causes ADHD in offspring. On July 25, plaintiffs submitted their response, in which they argue that summary judgment is improper because prior statements by one of the defendants' experts, Dr. Stephen

Faraone, provide sufficient admissible evidence to show general causation as to ADHD. An Order of July 26 set a schedule for briefing on this issue, which was fully submitted on August 16.

Discussion

Plaintiffs in this MDL have presented six experts to opine that prenatal exposure to acetaminophen can cause ADHD and/or ASD. The Court carefully considered each expert's proffered testimony and determined, in two separate opinions, that none of these experts presented reliable testimony on general causation. Plaintiffs now argue that they can satisfy their burden on general causation by presenting a handful of prior statements by one of defendants' experts, who has repeatedly opined that existing studies and data do not supply a reliable basis on which to find that acetaminophen can cause ADHD. Defendants argue that plaintiffs' new approach falls short of creating a genuine issue of material fact.

Summary judgment may be granted "only if there is no genuine issue of material fact and the prevailing party [is] entitled to judgment as a matter of law." Indemn. Ins. Co. of N. Am. v. Unitrans Int' l Corp., 98 F.4th 73, 77 (2d Cir. 2024) (citation omitted). "[S]ummary judgment must be rejected if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. (citation omitted). The court's

role is "not to resolve disputed questions of fact but solely to determine whether, as to any material fact, there is a genuine issue to be tried." Moll v. Telesector Res. Grp., Inc., 94 F.4th 218, 227 (2d Cir. 2024) (citation omitted).

In determining whether genuine issues of fact exist, the court "may not properly consider the record in piecemeal fashion." Id. (citation omitted). Instead, "the court must review the record taken as a whole." Id. (citation omitted). The court "may not make credibility determinations or weigh the evidence," but "reliance upon conclusory statements or mere allegations will not suffice to defeat summary judgment." Id. at 227-28 (citation and emphasis omitted). When a party has "failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof," summary judgment is proper. Id. at 228 (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). But if "the admissible materials in the record make it arguable that the claim has merit, then summary judgment dismissing a claim cannot be granted." Id. (citation and emphasis omitted).

In "cases where jurors are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training," expert testimony is unnecessary. Ojeda v. Metropolitan Transportation

Authority, 41 F.4th 56, 70 (2d Cir. 2022) (citation omitted). Where, however, a necessary element of a claim "would not be obvious to the lay juror," expert testimony is required. Id. (citation omitted).

"[E]xpert medical opinion evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within the sphere of the common knowledge of the lay person." Barnes v Anderson, 202 F.3d 150, 159 (2d Cir. 1999). Accordingly, the Court of Appeals for the Second Circuit has required expert testimony "to establish the causal link between exposure to toxins and other behavior and squamous cell carcinoma." Ojeda, 41 F.4th at 70 (citation omitted). See also In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation, 892 F.3d 624, 647 (4th Cir. 2018) ("Lipitor") (noting with approval the Second Circuit's observation that all fifty states typically require expert testimony to prove causation where the causal relationship is outside the common knowledge of lay jurors).

Causation in pharmaceutical products liability cases such as those in this MDL has two components, general and specific causation. General causation exists when a substance is capable of causing a particular injury or condition. Courts routinely

grant summary judgment for the defense in pharmaceutical product liability or toxic tort cases where plaintiffs fail to adduce reliable expert testimony establishing general causation. See, e.g., Mirena II, 982 F.3d at 125; Milward v. Rust-Oleum Corp., 820 F.3d 469, 476 (1st Cir. 2016) (noting expert testimony is required to establish medical causation under Massachusetts law); Amorgianos v. National R.R. Passenger Corp., 303 F.3d 256, 271 (2d Cir. 2002).

One generally accepted methodology for determining general causation among epidemiologists is consideration of the Bradford Hill criteria. These criteria are the metrics that epidemiologists use to distinguish a causal connection from mere association. First Daubert Opinion, 2023 WL 8711617, at *18. A court must ensure that an expert conducts a Bradford Hill analysis in a reliable manner. In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation, 858 F.3d 787, 795 (3d Cir. 2017) ("Zoloft"). Therefore, the expert must explain how conclusions are drawn for each Bradford Hill criterion and how the criteria are weighed relative to one another. Id. at 796.

The defendants have shown that they are entitled to summary judgment. The plaintiffs have failed to offer reliable expert testimony as to general causation. The Daubert Opinions in this

litigation have stricken the testimony proffered by the plaintiffs' experts on the issue of general causation. Without expert evidence, plaintiffs cannot meet their burden on an essential element of their case. Without such expert testimony, a lay juror could only find that prenatal exposure to acetaminophen causes ADHD in offspring by resorting to speculation.

Plaintiffs argue that summary judgment is improper because Dr. Faraone's prior statements will supply sufficient admissible evidence from which a jury could infer general causation, thereby creating a genuine issue of material fact. Plaintiffs suggest that a jury could find general causation based on 1) two brief excerpts from Dr. Faraone's day-long deposition testimony in this litigation; 2) Dr. Faraone's statements in peer-reviewed scientific literature or other formal documents; and 3) Dr. Faraone's prior unsworn statements, principally LinkedIn posts, which the plaintiffs contend can be admitted for purposes of impeachment (together, the "Faraone Evidence").

Dr. Faraone is a world-renowned expert on ADHD. He is a Distinguished Professor in the Departments of Psychiatry and Neuroscience & Physiology at the State University of New York Upstate Medical University and Vice Chair for Research in the Department of Psychiatry and Behavioral Sciences at that

University. He has performed original research on the diagnosis, etiology, and pathophysiology of ADHD and has published more than 840 articles on ADHD. In 2019, he was elected, and in 2023 re-elected, President of the World Federation of ADHD. In 2021, he coordinated the creation and publication of the World Federation of ADHD International Consensus Statement on ADHD,[5] one of the documents upon which plaintiffs rely. In Dr. Faraone's amended expert report of August 22, 2023, submitted on behalf of the defendants, he opined that there is no reliable scientific evidence that maternal use of acetaminophen causes ADHD in offspring. He noted that although more than 20 epidemiological studies had been published by that date, those studies did not support a causal inference.

The Faraone Evidence, even if admissible, would not permit a jury to find for plaintiffs on the element of general causation.[6] Even if cobbled together, the Faraone Evidence does not constitute a Bradford Hill analysis in support of

[5] Faraone et al., The World Federation of ADHD International Consensus Statement: 208 Evidence-based Conclusions about the Disorder, 128 Neuro. Biobehavioral Rev. 789 (2021) ("ADHD Consensus Statement").

[6] It is unnecessary to address the admissibility of the Faraone Evidence because, even if each statement were admissible, the statements would not constitute reliable evidence of general causation in support of the plaintiffs' theory.

plaintiffs' thesis. When Dr. Faraone examined the published scientific data using the Bradford Hill criteria, he found that

> the criteria do not support a causal inference. Strength of association is not satisfied because the reported associations are weak and influenced by confounding. The study results are inconsistent across different populations and measures. Many of the reported associations are not specific to ADHD. There is no clear dose response reported in the literature. And the association is not biologically plausible because there is no known pathophysiological mechanism of injury for the development of ADHD.

In none of the statements on which plaintiffs rely does Dr. Faraone state that prenatal exposure to acetaminophen causes ADHD in offspring. Instead, plaintiffs seize on fragments from Dr. Faraone's extensive writings and prior statements and misleadingly portray those fragments. When read in context, Dr. Faraone's statements and testimony do not support plaintiffs' theory of general causation. To the contrary, as his expert report and deposition testimony describe in considerable detail, his analysis is in line with the statements of public health organizations and regulatory agencies that there is no reliable evidence of a causal relationship between in utero exposure to acetaminophen and the development of ADHD. See First Daubert Opinion, 2023 WL 8711617, at *12-15; Second Daubert Opinion, 2024 WL 3357608, at *10-13.

Much of the Faraone Evidence falls into one of three buckets. First, there are several statements that do not even

refer to acetaminophen. They instead speak more generally to the fact that environmental risk factors may contribute to the development of ADHD even though ADHD is a highly heritable disorder.

Second, the majority of the statements merely acknowledge that studies have documented an association between prenatal acetaminophen exposure and ADHD. That this is so has never been a disputed proposition in this case. Plaintiffs' experts have conceded, however, that the association is weak or modest at best. And, as explained at length in both Daubert Opinions in this case, an association, by itself, does not establish causation; instead, further analysis must be conducted to assess whether the association is causal or is instead a result of chance, confounding, or bias. See, e.g., First Daubert Opinion, 2023 WL 8711617, at *5; Second Daubert Opinion, 2024 WL 3357608, at *5. Indeed, both Daubert Opinions thoroughly addressed the importance of confounding to this case. See, e.g., First Daubert Opinion, 2023 WL 8711617, at *31-*33; Second Daubert Opinion, 2024 WL 3357608, at *19-*21. A jury would not be permitted to return a verdict based on a possibility of causation. As the Fourth Circuit Court of Appeals has observed, where "most of the statements" proffered by plaintiffs to defeat summary judgment "speak to association rather than causation,"

asking a jury "to reach a conclusion as to causation with any amount of certainty would be farcical and would likely result in a verdict steeped in speculation". Lipitor, 892 F.3d at 647.

As for the third collection of statements, plaintiffs point to statements by Dr. Faraone (or his co-authors) which refer to acetaminophen as a "risk factor" for ADHD. But Dr. Faraone repeatedly explained in his deposition that the term "risk factor" is a synonym for "correlate" and that "it's not the same as cause." Indeed, he specified that the term "risk factor" "is sometimes misinterpreted by lay people" to mean cause, highlighting the impropriety of inviting a jury to speculate as to whether a patchwork of Dr. Faraone's out-of-context statements, rather than his expert opinion to the contrary, proves general causation.

The plaintiffs place the most weight on two brief excerpts from Dr. Faraone's deposition in this litigation, which they construe as admissions that acetaminophen exposure causes ADHD. In one excerpt, Dr. Faraone is shown a slide he created on the causes of ADHD, which lists modifiable environment risk factors as including exposure to acetaminophen. As already explained, and as Dr. Faraone explained in his deposition, identifying a behavior or a substance as a risk factor is not a finding of causation; it is identifying a correlation.

In the second excerpt from his deposition, Dr. Faroane is questioned about "Statement 38" in the ADHD Consensus Statement. Statement 38 describes a Taiwanese study that found an association between in utero exposure to acetaminophen and a 33% greater likelihood of developing ADHD during childhood.[7] Statement 38 is one of twelve statements or paragraphs describing individual studies of "Environmental correlates of ADHD: exposure to toxicants." Even though Statement 38 did not speak in terms of causation, plaintiffs' counsel inquired as follows: "Statement 38 represents one of the evidence-based conclusions that the scientific community has concluded regarding the causes of ADHD, right?" Dr. Faraone answered "Yes, that's correct". After further discussion, plaintiffs' counsel inquired again about Statement 38, asking, "was one of the evidence-based findings that . . . acetaminophen during pregnancy is associated with a 33 percent greater likelihood of ADHD in children?" Dr. Faraone responded, "That's a Taiwanese study, correct." In his second question, plaintiffs' counsel correctly characterized Statement 38. Dr. Faraone's failure to catch and correct the mischaracterization in the first question

[7] The study in question -- the results of which were addressed in both Daubert Opinions in this case -- is Chen et al., Prenatal Exposure to Acetaminophen and the Risk of Attention-Deficit/Hyperactivity Disorder: A Nationwide Study in Taiwan, 80(5) J. Clin. Psychiatry (2019).

about Statement 38 does not provide a reliable basis to find that Dr. Faraone's true opinion is that acetaminophen exposure causes ADHD.

Even though none of these statements, either singly or together, constitutes a methodical analysis of the issue of causation, plaintiffs suggest that, "[g]iven the sheer number of Dr. Faraone's inconsistent statements coupled with his published pre-litigation statements, a reasonable jury could conclude that prenatal exposure to acetaminophen can in fact cause ADHD." They argue that

> [t]he Faraone evidence, construed in the light most favorable to Plaintiffs, can reasonably support the following factual findings: (1) there is a positive and statistically significant association between prenatal acetaminophen exposure and ADHD; (2) there is a dose-response relationship between acetaminophen exposure and ADHD; (3) it "makes biological sense" that prenatal acetaminophen exposure can cause ADHD; (4) environmental risk factors play a role in causing ADHD; and (5) acetaminophen is one of the environmental risk factors that plays a role in causing ADHD.

Plaintiffs propose that a jury stitch the above propositions together to find general causation despite the fact that Dr. Faraone has repeatedly stated -- both in his 98-page amended expert report for the defendants, which plaintiffs ignore, and in his deposition in this litigation -- that there is no reliable scientific evidence that maternal use of acetaminophen causes ADHD in offspring. Even setting aside the

fact that the plaintiffs have mischaracterized Dr. Faraone's prior statements, their proposal also fundamentally misunderstands the process by which scientists assess the issue of general causation. "Drawing causal inferences after finding an association and considering [the Bradford Hill] factors requires judgment and searching analysis, based on biology, of why a factor or factors may be absent despite a causal relationship." Reference Manual on Scientific Evidence (3d ed. 2011) ("RMSE") at 600. Plaintiffs' proposal -- that a series of disparate scientific observations is adequate for a jury to find general causation -- is not viable. The issue of general causation in this litigation is complex and serious. Juries are entitled to a thoughtful, reliable analysis by a qualified expert.

No reasonable jury could find, from the smattering of Dr. Faraone's past statements and isolated pieces of his deposition identified by plaintiffs, that prenatal exposure to acetaminophen can cause ADHD in offspring. As such, plaintiffs have failed to make a sufficient showing on an essential element of their case with respect to which they have the burden of proof. Summary judgment is therefore granted for defendants.[8]

[8] The defendants argue that plaintiffs' response to the July 11 show cause Order has vexatiously multiplied proceedings, entitling defendants to fees and costs incurred in preparing

Conclusion

Final judgment is entered for defendants in all pending member cases. The Clerk of Court is directed to enter judgment for defendants and to close all pending member cases.

Dated: New York, New York
August 20, 2024

DENISE COTE
United States District Judge

their response pursuant to 28 U.S.C. § 1927. It bears noting that the plaintiffs' reliance on cherry-picked statements by a defense expert to fill the gap in their own evidence of general causation appears to be an established litigation tactic to resist summary judgment. See, e.g., In re Mirena IUS Levonorgestrel-Related Products Liability Litigation, 387 F. Supp. 3d 323, 350-52. This tactic has been consistently rejected by courts. Nonetheless, any award of sanctions must be supported by an explicit finding of bad faith. See Rossbach v. Montefiore Medical Center, 81 F.4th 124, 143 (2d Cir. 2023). In the absence of a formal motion, the defendants' argument will not be further considered.